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PTO/SB/21 (08-03) Approved for use through 08/30/2003. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE nder the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number Application Number 10/702,578 TRANSMITTAL Filing Date 11/05/03 **FORM** First Named Inventor Tae-Wan Kim Art Unit (to be used for all correspondence after initial filing) 1632 **Examiner Name** to be assigned Attorney Docket Number 5199-14 Total Number of Pages in This Submission **ENCLOSURES** (Check all that apply) After Allowance communication Fee Transmittal Form Drawing(s) to Technology Center (TC) Appeal Communication to Board Licensing-related Papers Fee Attached of Appeals and Interferences Appeal Communication to TC Petition (Appeal Notice, Brief, Reply Brief) Amendment/Reply Petition to Convert to a Proprietary Information After Final **Provisional Application** Power of Attorney, Revocation Status Letter Affidavits/declaration(s) Change of Correspondence Address Other Enclosure(s) (please Terminal Disclaimer **Extension of Time Request** Identify below): Return receipt postcard Request for Refund **Express Abandonment Request** CD, Number of CD(s) Information Disclosure Statement Remarks Certified Copy of Priority Document(s) Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Todd Holmbo, Reg. No. 42,665 Individual name Signature Date 9124104 CERTIFICATE OF TRANSMISSION/MAILING I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below. Typed or printed name Ping Xiao Rico

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

re Application of: Tae-Wan Kim Docket No.: 5199-14

Serial No.: 10/702,578 Examiner: to be assigned

Filed: November 5, 2003 Group Art Unit: 1632

Title: NOVEL MODULATORS OF AMYLOID-BETA PRODUCTION

AND USES THEREOF

September 24, 2004

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

<u>INFORMATION DISCLOSURE STATEMENT</u> <u>UNDER 37 CFR §1.97(b)</u>

Sir:

In accordance with the duty of disclosure under 37 CFR §1.56, applicant hereby notifies the U. S. Patent and Trademark Office of the following documents, which are listed on the attached PTO/SB/08B form. The examiner may deem these documents to be relevant to patentability of the claims of the above-identified application. Copies of the documents are enclosed for the examiner's convenience.

The submission of the listed documents is not intended as an admission that any of the documents constitute prior art against the claims of the present application. Applicants do not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Applicants respectfully request that the listed documents be considered by the examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08B be returned in accordance with MPEP §609.

It is understood that no fee is necessary for submission of this Information Disclosure Statement, as it is being filed before the later of three months from the filing date or the mailing of the first Office Action on the merits. The Commissioner is hereby authorized to charge payment of any fees associated with this application or credit any overpayment to Deposit Account No. 02-4270.

Respectfully submitted,

Todd Holmbo

Reg. No. 42,665

Attorney for Applicants

BROWN RAYSMAN MILLSTEIN

FELDER & STEINER LLP

163 Madison Avenue

P.O. Box 1989

Morristown, New Jersey 07962-1989

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PTO/SB/08B (08-03)

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der the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Substitute for form 1449/PTO **Application Number** 10/702,578 Filing Date INFORMATION DISCLOSURE 11/05/03 STATEMENT BY APPLICANT **First Named Inventor** Tae-Wan Kim Art Unit 1632 (Use as many sheets as necessary) **Examiner Name** to be assigned Attorney Docket Number Sheet 10 5199-14

		NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), tit the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-is number(s), publisher, city and/or country where published.					
		Annaert et al., Interaction with telencephalin and the amyloid precursor protein predicts a ring structure for presenilins.				
`		Neuron, 32: 579-89, 2001				
		Armogida et al., Endogenous beta-amyloid production in presenilin-deficient embryonic mouse fibroblasts.				
		Nat. Cell Biol., 3:1030-33, 2001				
		Ausubel et al., Current Protocols in Molecular Biology, New York: John Wiley and Sons, New York, 1997 (/ // A)				
		Caplen et al., dsRNA-mediated gene silencing in cultured Drosophila cells: a tissue culture model for the analysis of RNA interference.				
		Gene, 252:95-105, 2000				
		Chen et al., Nicastrin binds to membrane-tethered Notch.				
		Nat. Cell Biol., 3:751-54, 2001				

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Signature	Considered	

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		Chung and Struhl, Nicastrin is required for Presenilin-mediated transmembrane cleavage in Drosophila.					
		Nature Cell Biol., 3:1129-32, 2001					
		Cupers et al., The discrepancy between presenilin subcellular localization and gamma-secretase processing of amyloid precursor protein.					
	J. Cell Biol., 154:731-40, 2001						
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		De Strooper and Annaert, Presenilins and the intramembrane proteolysis of proteins: facts and fiction.					
		Nat. Cell Biol., 3:E221-25, 2001					
		Ebinu and Yankner, A rip tide in neuronal signal transduction.					
		Neuron, 34:499-502, 2002					

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		Elbashir et al., Duplexes of 21-nucleotide RNAs mediate RNA interference in cultured mammalian cells.					
		Nature, 411: 494-98, 2001					
		Elbashir et al., Functional anatomy of siRNAs for mediating efficient RNAi in Drosophila melanogaster embryo lysate.					
		EMBO J., 20:6877-88, 2001					
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		Genes Dev., 15:188-200, 2001					
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		Proc. Natl. Acad. Sci. USA, 99:2720-25, 2002					
		Esler et al., Transition-state analogue inhibitors of gamma-secretase bind directly to presenilin-1.					
		Nature Cell Biol., 2:428, 2000					

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		Fire, A. RNA-triggered gene silencing.	
		Trends Genet., 15:358-63, 1999	
		Francis et al., Neuregulins and ErbB receptors in cultured neonatal astrocytes.	
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		Proc. Natl. Acad. Sci, USA, 99:775-79, 2002	
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		Nature, 404:293-96, 2000	
		Hardy, J., Amyloid, the presenilins and Alzheimer's disease.	
		Trends Neurosci., 20:154-59, 1997	

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		Hu and Fortini, Nicastrin is required for gamma-secretase cleavage of the Drosophila Notch receptor.	
		Dev. Cell, 2:69-78, 2002	
		Kehoe et al., A full genome scan for late onset Alzheimer's disease.	
		Hum. Mol. Genet., 8:237-45, 1999	
		Kim et al., Endoproteolytic cleavage and proteasomal degradation of presenilin 2 in transfected cells.	
		J. Biol. Chem., 272:11006-010, 1997	
		Levitan and Greenwald, Facilitation of lin-12-mediated signaling by sel-12, a Caenorhabditis elegans S182 Alzheimer's disease gene.	
		Nature, 377:351-54, 1999	

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		L' Hernault and Arduengo, Mutation of a putative sperm membrane protein in Caenorhabditis elegans prevents sperm differentiation but not			
		its associated meiotic divisions.			
		J. Cell. Biol., 119:55-58, 1992			
		Li and Greenwald, HOP-1, a Caenorhabditis elegans presenilin, appears to be functionally redundant with SEL-12 presenilin and to facilitate LIN-12			
		and GLP-1 signaling.			
		Proc. Natl. Acad. Sci. USA, 94:12204-209, 1997			
		Li, et al., Presenilin 1 is linked with gamma-secretase activity in the detergent solubilized state.			
		Proc. Natl. Acad. Sci. USA, 97:6138-43, 2000			
		Li, et al., Photoactivated gamma-secretase inhibitors directed to the active site covalently label presenilin 1.			
		Nature, 405:689-94, 2000			

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		Lopez-Schier and St. Johnston, Drosophila nicastrin is essential for the intramembranous cleavage of notch.	
		Dev. Cell, 2:79-89, 2002	
		Myers et al., Full genome screen for Alzheimer disease: Stage II analysis.	
		Am. J. Med. Genet., 114:235-44, 2002	
		Naruse et al., Effects of PS1 deficiency on membrane protein trafficking in neurons.	
		Neuron, 21:1213-21, 1998	
		Seiffert et al., Presenilin-1 and -2 are molecular targets for gamma-secretase inhibitors.	
		J. Biol. Chem., 275:34086-091, 2000	
		Selkoe, D.J., Alzheimer's disease: gene, proteins, and therapy.	
		Physiol. Rev., 81:741-66, 2001	

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		Sisodia and George-Hyslop, gamma-Secretase, Notch, alpha-beta and Alzheimer's disease: where do the presenilins fit in?		
		Nat. Rev. Neurosci., 3:281-90, 2002		
		Steiner and Haass, Intramembrane proteolysis by presenilins.		
		Nat. Rev. Mol. Cell Biol., 1: 217-24, 2000		
		Taniguchi et al., Notch receptor cleavage depends on but is not directly executed by presenilins.		
		Proc. Natl. Acad. Sci. USA, 99:4014-19, 2002		
		Tanzi et al., The gene defects responsible for familial Alzheimer's disease.		
		Neurobiol. Dis., 3:159-68, 1996		
		Thinakaran et al., Endoproteolysis of presenilin 1 and accumulation of processed derivatives in vivo.		
		Neuron, 17:181-90, 1996		

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		Thinakaran et al., Evidence that levels of presenilins (PS1 and PS2) are coordinately regulated by competition for limiting cellular factors.			
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		Worby et al., RNA interference of gene expression (RNAi) in cultured Drosophila cells.			
		Sci. STKE, 95:PL1, 2001			

Examiner	Date	<u> </u>
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0000	3 10 10 11 14 10 17 10			Application Number	10/702,578
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Filing Date	11/05/03
				First Named Inventor	Tae-Wan Kim
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				Examiner Name	to be assigned
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		Yu et al., Nicastrin modulates presenilin-mediated notch / glp-1 signal transduction and betaAPP processing.	
		Nature, 407:48-54, 2000	
		Zubenko et al., A genome survey for novel Alzheimer disease risk loci: results at 10-cM resolution.	
		Genomics, 50:121-28, 1998	

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